

**REMARKS**

Claims 1-3, 9-17, 19-22, 28-36, 38-41, 47-55, 57-60, 66-74, 76-79, 85-93 and 95 are pending in the application. Claims 11-14, 30-33, 49-52, 68-71, and 87-90 are withdrawn as drawn to processes that use the antibodies of the invention. Applicants respectfully request that these claims be rejoined to the invention upon finding the elected claims allowable and examined in this application. Claims 1-3, 9, 15-17, 19-22, 28, 29, 34-36, 38-41, 47, 53-55, 57-60, 66 and 72-74 are allowable. The proposed claim 76 recites "[a]n isolated population of monoclonal mammalian anti-Dengue virus antibody." Support for this amendment is found throughout the specification, and particularly in paragraphs [0051]-[0052]. It is submitted that no new matter has been introduced by the present proposed amendment and entry of the same is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

Applicants note with appreciation that the objections and rejections of claims 1-3, 9, 15-17, 19-22, 28, 29, 34-36, 38-41, 47, 53-55, 57-60, 66 and 72-74 have been withdrawn. Specifically, the objection to the specification due to embedded hyperlinks has been withdrawn. The objection to claims 1-3, 9, 10, 15-17, 19-22, 28, 29, 34-36, 38-41, 47, 48, 53-55, 57-60, 66, 67, 72-74, 76-79, 91-93 and 95 due to alleged recitation of non-elected subject matter has been withdrawn. Finally, the rejection of claims 1-3, 10, 15, 19-22, 29, 34, 38-41, 47-48, 57-60, 66-67, 72-74, 76, 85, 86 and 95 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite has been withdrawn.

**I. Rejections under 35 U.S.C. § 112, second paragraph**

Claims 77-79 and 91-93 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Office Action mailed June 13, 2006, page 3. Applicants respectfully traverse.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576,

1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

The Examiner alleges that the phrase “to the entire amino acid sequence of a Dengue virus NS protein” is unclear. Office Action mailed June 13, 2006, page 3. This phrase was never asserted to be unclear in the Office Action mailed December 6, 2005. *See* Office Action mailed December 6, 2005, pages 3-4. Accordingly, Applicants have not had the opportunity to address this ground of rejection and they respectfully request that this Office Action should be made non-final.

None-the-less, Applicants respectfully submit that one of skill in the art would understand the phrase “to the entire amino acid sequence of a Dengue virus NS protein.” In the context of claims 77, 91 and 92, the antibody binds “at least one epitope,” therefore may bind more than on epitope, “comprising ... to the entire amino acid sequence of a Dengue virus NS1 protein.” One of skill in art would understand that an epitope may comprise the entire sequence of a Dengue virus NS protein. The breadth of a claim is not to be equated with indefiniteness.

Accordingly, Applicants respectfully request that the present rejections of claims 77-79 and 91-93 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

## **II. Rejections under 35 U.S.C. 112, first paragraph**

Claims 10, 48, 67 and 86 are newly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action mailed June 13, 2006, page 3. Applicants respectfully traverse.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). An applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which make it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc. that set forth the claimed invention”. *Regents of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1666 (Fed. Cir. 1997).

The Examiner does not explain why this new rejection is brought in an Office Action that is deemed final. Indeed, the list of compounds in claims 10, 48, 67 and 86 were not amended in the last Office Action. Therefore the Applicants did nothing in the last Reply to necessitate this new rejection. Accordingly, Applicants respectfully request that this Office Action be made non-final.

The Examiner alleges that the specification does not provide sufficient recitation of distinguishing identifying characteristics of the claimed genus in claims 10, 48, 67 and 86. However, all of the varieties of molecules listed in the rejected claims are well known to those of skill in the art. Therefore, one of skill in the art would be able to envision the structures described in each class of molecules and the activity of the molecule, i.e. analgesic, sedative, local anesthetic etc.. Further, specific examples of molecules are provided in the specification in paragraphs [0107] – [0108], as well as references which may be used to find additional molecules and dosage ranges. Therefore, there is sufficient structure/function description of this genus of molecules that one of skill in the art could conclude that the inventors had possession of the invention.

Accordingly, Applicants respectfully request that the rejection of claims 10, 48, 67 and 86 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

### **III. Rejections under 35 U.S.C. § 102(b)**

Claims 76-79, 85-86, 91-93, and 95 are rejected under 35 U.S.C. § 102(b) as being anticipated by Valdés *et al.* (*Clinical and Diagnostic Laboratory Immunology*, 2000, 7(5):856-857, “Valdés”). Office Action, page 6. Applicants respectfully traverse.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is “known to the art in the detail of the claim.” *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be “arranged as in the claim.” *Id.* Valdés does not teach or disclose every element of the claimed invention.

Again, the present rejection under 35 U.S.C. § 102(b) over Valdés is a new rejection. Claim 76 was not rejected in the prior Office Action on these grounds. Therefore, Applicants

have not had the opportunity to address this new ground of rejection of claim 76. The amendment made to claim 76 in the Response of March 31, 2006 merely incorporated the recitation of claim 75, now cancelled, into claim 76, and did not change the scope or language of claim 76. Therefore, this amendment did not necessitate a new rejection. Further, the present rejection over Valdés is based on a different argument than that of the last Office Action. The present Examiner argument relates to a syringe used to draw blood, while the previous argument relates to a syringe used to load a polyacrylamide gel. Office Action mailed June 13, 2006, page 8; Office Action mailed December 6, 2005, page 6. Applicants respectfully request that the present Office Action be made non-final.

None-the-less, the proposed amendment to claim 76 recites “an isolated population of monoclonal antibodies.” As stated in the response filed March 31, 2006, Valdés does not teach or disclose a population of monoclonal antibodies, and particularly an isolated population of monoclonal antibodies. The Examiner does not address this argument in the current Office Action. Valdés does not disclose the antibodies in the human sera to be “isolated” from the sera in any way. Further, it is well known to those in the art that human sera contains a broad polyclonal population of antibodies, and therefore is not a (one) monoclonal population. See Charles A. Janeway *et al.*, *Immunobiology*, 46 (1999). Valdés does not disclose a “population of monoclonal mammalian anti-Dengue virus antibody” or “an isolated population of monoclonal mammalian anti-Dengue virus antibody” as recited in independent claims 76, 77, 91, 92, and 95, and therefore does not teach or disclose every element of the claimed invention.

Valdés does not teach or disclose “[a] medical device, comprising at least one isolated mammalian anti-Dengue virus antibody” as recited in independent claim 91, or a “packaging material and a container comprising at least one isolated mammalian anti-Dengue virus antibody” as recited in independent claim 92. The extraction of serum samples from patients, as was done in Valdés, would not necessarily use a syringe or other medical device “suitable for contacting or administering said anti-Dengue virus antibody.” There are other methods to extract blood serum, such as pricking a finger. Further, a syringe cannot be both container and packaging material as suggested by the Examiner as they are clearly delineated in the claim as separate items. Office Action mailed June 13, 2006, page 8. Therefore, Valdés does not teach or disclose “[a] medical device, comprising at least one isolated mammalian anti-Dengue virus antibody” as recited in independent claim 91, or a “packaging material and a

container comprising at least one isolated mammalian anti-Dengue virus antibody” as recited in independent claim 92, and therefore does not teach or disclose every element of the claimed invention.

Valdés does not teach or disclose an anti-Dengue virus antibody in “at least one pharmaceutically acceptable carrier or diluent” as recited in independent claim 85. The Examiner suggests that the “pharmaceutically acceptable carrier” is in the Western blot diluent. Office Action mailed June 13, 2006, page 7. The contents of Western blot diluent are not taught or described in Valdés. One of skill in the art would not necessarily find a “pharmaceutically acceptable diluent” in a Western blot diluent. One popular Western blot diluent contains non-fat dried milk, antifoam A and sodium azide. *See J. Sambrook et al., Molecular Cloning* 18.72 (1989), attached. All three of these components are not acceptable for a pharmaceutical diluent. Sodium azide in particular is known to be a toxic substance. *See Sodium Azide*, International Chemical Safety Card No. 0950, attached. Therefore, Valdés does not teach or disclose an anti-Dengue virus antibody in “at least one pharmaceutically acceptable carrier or diluent” as recited in independent claim 85.


Accordingly, Applicants respectfully request that any rejections of claims 76-79, 85-86, 91-93, and 95 under 35 U.S.C. § 102(b) over Valdés be reconsidered and withdrawn.

**Conclusion**

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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